REMARKS

Claim 1 has been amended to include a definition of a "compound signal" as used in the specification, particularly as used in paragraph [0022]. Claim 13 has been canceled and placed in independent form as new claim 19. Applicant notes that claim 19 is not limited to application of the signal to the knee joint but is instead directed to the treatment of cancer and in the prevention of metastases in cancer. No other claim has been amended and no new matter has been added. Upon entry of this amendment, claims 1-12, 14, and 19 will be in the application.

Claim Objections

Claim 13 stands objected to under 37 CFR 1.75(b) as allegedly not substantially differing from claim 1. Applicant disagrees. Unlike claim 1, claim 13 further specifies that the generated compound electric signals down-regulate the gene expression of other proteases in addition to metalloproteases for the treatment of cancer and in the prevention of metastases in cancer. However, since it is desired to not limit the use of the device for the treatment of cancer and in the prevention of metastases in cancer in just the knee but to also use the device for treatment of cancer and in the prevention of metastases in cancer in other tissues and regions of the body, claim 13 has been redrafted in independent form as new claim 19. Claim 13 has accordingly been canceled. Withdrawal of the objection to claim 13 is respectfully requested.

Claim Rejections - 35 USC § 102

Brighton '775

Claims 1 .2, 7-10, and 13 stand rejected under 35 U.S.C.102(b) as allegedly being anticipated by Brighton et al . (U .S. Patent No . 4,535,775). This rejection is traversed.

Claim 1 recites a device for generating "specific and selective signals" for application to a capacitive coupling and/or inductive coupling device for the generation of selective electric or electromagnetic fields in defective or diseased tissue in a human knee joint for the treatment of such tissues. The desired fields are generated by communicating compound electric signals from a signal generator for application to a capacitive and/or inductive

coupling device that generates the desired fields in the tissues. As set forth in claim 1, the signal generator:

> generates compound electric signals that selectively up-regulate at least one of Aggrecan gene expression and Type II Collagen gene expression and selectively down-regulates metalloprotease gene expression, said compound electric signals comprising respective signals each having a given duration, amplitude, frequency and duty cycle that is selective for regulating Aggrecan, Type II Collagen and/or metalloprotease gene expression.

Such a device is not taught by Brighton '775.

Brighton '775 relates to a method and device for the treatment of non-union bone fractures through application of symmetrical waveform signals in the frequency range of 20-100 kHz and an amplitude value in the range of 2-10 volts peak to peak. Brighton '775 provides no teaching of the claimed "compound signal" that comprises "respective signals each having a given duration, amplitude, frequency and duty cycle that is selective for regulating Aggrecan, Type II Collagen and/or metalloprotease gene expression" as claimed in independent claim 1. On the contrary, Brighton '775 teaches the continuous application of a simple signal for the stimulation of fracture healing. Brighton '775 thus teach the application of a simple signal for a completely different condition and do not recognize the desirability of generating the claimed "compound signal" for the selective treatment of defective or diseased tissue so as to selectively regulate gene expression of those proteins (*e.g.*, Aggrecan, Type II Collagen and metalloprotease) that are implicated in the disease state. Accordingly, the claimed signal generator of independent claim 1 is not taught or suggested by Brighton '775. Withdrawal of the rejection of claim 1 and all claims dependent thereon is thus solicited.

Claims 7-10 also stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Brighton et al. (U.S. Patent No. 4,535,775) or, in the alternative, under 35 U.S.C. 103(a) as allegedly being obvious over Brighton et al. '775 in view of Ryaby et al. (U .S. Patent No. 4,266,533). This rejection is also traversed.

As noted above, Brighton '775 does not teach generation or application of the claimed "compound signal." Inasmuch as Ryaby et al. is cited for a purported teaching of "means for

holding" the signal generator to the patient's leg and does not teach the claimed "compound signal," even if the teachings of Ryaby et al. could have been combined with the teachings of Brighton '775 as the Examiner alleges, the claimed invention would not have resulted. Accordingly, the device of claims 7-10 is not believed to be anticipated by Brighton '775 or rendered obvious by Brighton '776 in view of Ryaby et al. Withdrawal of the rejection of claims 7-10 is thus solicited.

Dugot

Claims 1 and 2 stand rejected under 35 U .S.C.102(b) as allegedly being anticipated by Dugot (U.S. Patent No. 4,600,010) and/or Fleming (U .S. Patent No . 5,690,692). This rejection is traversed.

Dugot discloses an electric stimulator that applies a 60 kHz signal "treatment signal" with maximum amplitude of 6.3 volts peak-to-peak. Applicant cannot find where Dugot indicates what the "treatment signal" is designed to treat or what effect the "treatment signal" is to achieve in the body being treated. Dugot also provides no teaching of the claimed "compound signal" that comprises "respective signals each having a given duration, amplitude, frequency and duty cycle that is selective for regulating Aggrecan, Type II Collagen and/or metalloprotease gene expression" as claimed in independent claim 1. On the contrary, Dugot teaches the continuous application of a simple "treatment signal" for some unspecified treatment. Dugot also does not recognize the desirability of generating the claimed "compound signal" for the selective treatment of defective or diseased tissue so as to selectively regulate gene expression of those proteins (*e.g.*, Aggrecan, Type II Collagen and metalloprotease) that are implicated in the disease state. Accordingly, the claimed signal generator of independent claim 1 is not taught or suggested by Dugot. Withdrawal of the rejection of claims 1 and 2 is thus solicited.

Fleming

Fleming discloses a "bio-active" frequency generator that generates "bio-active" frequencies in the range of 0.0004 Hz to 3 MHz using a square wave having an amplitude that is adjusted using a variable resistor. Fleming lists numerous conditions and disease states and suggests frequencies that will treat the designated condition or disease state. However, Fleming provides no teaching of the claimed "compound signal" that comprises "respective signals each having a given duration, amplitude, frequency and duty cycle that is

selective for regulating Aggrecan, Type II Collagen and/or metalloprotease gene expression" as claimed in independent claim 1. Fleming also does not recognize the desirability of generating the claimed "compound signal" for the selective treatment of defective or diseased tissue so as to selectively regulate gene expression of those proteins (*e.g.*, Aggrecan, Type II Collagen and metalloprotease) that are implicated in the disease state. Accordingly, the claimed signal generator of independent claim 1 is not taught or suggested by Fleming. Withdrawal of the rejection of claims 1 and 2 is thus solicited.

Claim Rejections - 35 USC § 103

Claim 11 stands rejected under 35 U .S.C. 103(a) as allegedly being obvious over Brighton et al. (U.S. Patent No. 4,535,775) in view of Erickson et al. (U.S. Patent 5,565,005). This rejection is traversed.

Erickson et al. disclose an implantable growth tissue stimulator that is controlled and monitored by an external device. Erickson et al. is cited by the Examiner for his purported teaching of a wireless connection in a device that applies electromagnetic fields to promote healing at an injury site. However, Erickson et al. provide no teaching of the claimed "compound signal" that comprises "respective signals each having a given duration, amplitude, frequency and duty cycle that is selective for regulating Aggrecan, Type II Collagen and/or metalloprotease gene expression" as claimed in independent claim 1. Erickson et al. do not recognize the desirability of generating the claimed "compound signal" for the selective treatment of defective or diseased tissue so as to selectively regulate gene expression of those proteins (*e.g.*, Aggrecan, Type II Collagen and metalloprotease) that are implicated in the disease state. Accordingly, even if the teachings of Erickson et al. could have been combined with the teachings of Brighton '775 as the Examiner suggests, the claimed signal generator of independent claim 1 would not have resulted. Withdrawal of the rejection of claim 11 is thus solicited

Allowable Subject Matter

Applicant appreciates the Examiner's indication that claims 3-6, 12 and 14 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In view of the fact that these claims depend from independent

claim 1, which is believed to be allowable for the reasons given above, these claims have not been placed in independent form at this time. Applicant reserves the right to place these claims in independent form at a later time as appropriate.

New Claim 19

Applicant notes that new independent claim 19 includes the subject matter of original claims 1 and 13 and is believed to be allowable for the same reasons as recited herein with respect to claim 1. Allowance of claim 19 is thus solicited.

Conclusion

For the reasons noted herein, claims 1-12, 14, and 19 are believed to be allowable over the cited prior art. Allowance of the present patent application and issuance of a Notice of Allowability are respectfully requested.

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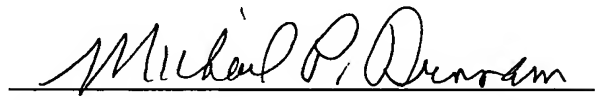

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